

Bureau of Naturopathic Medicine
Revised Final Statement of Reasons

Hearing Date: February 23, 2005

Subject Matter of Proposed Regulations:

Bureau of Naturopathic Medicine

Section(s) Affected:

16 CCR 4200, 4202, 4204, 4206, 4208, 4210, 4212, 4214, 4216, 4218, 4220, 4222, 4224, 4226, 4228, 4230, 4232, 4234, 4236, 4240, 4242, 4244, 4246, 4248, 4250, 4252, 4254, 4256, 4258, 4260, 4262, 4264, 4266, and 4268.

Specific Purpose of each adoption, amendment, or repeal:

The purpose for the adoption of these regulations is to implement the Naturopathic Doctor's Act and to establish the licensing role and responsibilities of the newly established Bureau of Naturopathic Medicine as enacted by Senate Bill (SB) 907 (Chapter 485, Statutes of 2003). The adoptions of the regulations will allow the Bureau to commence the licensure requirements for those individuals who desire to become naturopathic doctors in California.

This regulatory action adds Division 40 to Title 16 of the California Code of Regulations. Specifically, this regulatory action adds the following sections:

Article 1. General Provisions

1. Adds Section 4200.

This section establishes the purpose of these regulations – to implement and make specific the statutory provisions of the Naturopathic Doctors Act. This introduces the public to the bases for the regulations.

2. Adds Section 4202.

This section specifies that the principal office of the Bureau is located in Sacramento, California. This provides applicants and the members of the public with the physical address of the Bureau.

3. Adds Section 4204.

This section requires persons issued a certificate or license by the Bureau to: 1) notify the Bureau of his or her current address including an address of record for public information; and 2) notify the Bureau within fourteen (14) days of any changes of address. This allows the Bureau to maintain current address information of all licensees and certificate holders and to disclose their addresses of record to the members of the public.

4. Adds Section 4206.

This section establishes the regulatory definition of various terms. This defines frequently used terms within the regulations that are not defined by statute.

5. Adds Section 4208.

This section establishes the conditions under which the Bureau will disclose complaint information. This allows the Bureau to collect complaint data information to produce a complaint history report for the members of the public.

Article 2. Applications

6. Adds Section 4210.

This section specifies that completed applications for licensure or certification are to be filed at the Bureau's principal office in Sacramento. This informs applicants of the location of filing.

7. Adds Section 4212.

This section specifies the contents of an application for licensure as a naturopathic doctor and also specifies that the application fee is not refundable. This allows the Bureau to collect the information necessary to assess each applicant's qualifications in meeting the required training, competency, and criminal history clearance as conditions of licensure.

8. Adds Section 4214.

This section specifies the contents of an application for a certificate of registration and the duration of said certificate, and the renewal process for the certificate. This allows the Bureau to grant a certificate of registration to practice naturopathic medicine to an individual who is not a licensee and holds a faculty position at an approved naturopathic medical education program.

9. Adds Section 4216.

This section specifies that the Bureau shall notify applicants as to the completeness of their application within one hundred (100) working days of receipt. This section also specifies that within one hundred (100) working days of the filing of a complete application, the Bureau shall notify applicants whether the application has been approved or denied. This allows the Bureau a specific timeframe to assess an application and inform the applicant if his/her application is complete for filing or what required information or documentation is missing for filing.

10. Adds Section 4218.

This section specifies under which conditions applications filed with the Bureau may be considered abandoned and that upon abandonment, the application fee is forfeited to the Bureau. This allows the Bureau, after a specific timeframe that no action has been made from the applicant, to purge abandoned, incomplete applications from its files.

Article 3. Examinations

11. Adds Section 4220.

This section establishes the Naturopathic Physicians Licensing Examination (NPLEX) as the licensing examination and provides an exception to those applicants who have graduated from an approved naturopathic medical school prior to January 1, 1986. This allows the Bureau to specify the examination required for licensure and set the passing score.

Article 4. Licenses

12. Adds Section 4222.

This section specifies that the duration of a license is two years from the last day of the second birth month and establishes the requirements for license renewal. This allows the Bureau set a licensee's renewal date to coincide with his/her birth month.

13. Adds Section 4224.

This section specifies that a naturopathic doctor's license must be displayed under glass or other transparent material in an area frequented by patients. This is to verify licensure for patients and inform them as to the identity of the regulatory agency they may contact if they have any questions or complaints regarding the licensee.

14. Adds Section 4226.

This section specifies the requirements for a licensee to renew an expired license or certificate and the fees required for renewal. This provides the procedure for renewal of an expired license. A license not renewed within three years after it expired, the Bureau may impose on a case-by-case basis a condition of competency, such as retaking and passing NPLEX, before licensure. The Bureau will take into consideration how long the license has been expired and if all or any of the required number of hours for continuing education has been satisfied.

15. Adds Section 4228.

This section specifies the requirements for a license to be placed on inactive status. This allows a licensee or certificate holder who is not actively engaged in his/her professional practice to maintain licensure or certification in a nonpracticing status.

Article 5. Schools

16. Adds Section 4230.

This section addresses approval of naturopathic medical schools. Naturopathic medical schools that have been accredited or is a candidate for accreditation by the Council on Naturopathic Medical Education are deemed approved by the Bureau. Candidate for accreditation is a status of affiliation that indicates a naturopathic medicine program meets CNME's eligibility requirements, complies with its standards to the degree expected for its state of development, is progressing toward accreditation by CNME, and its students and graduates are eligible to apply for NPLEX administered by NABNE. This section also requires the Bureau to maintain a list of approved schools. Despite a diligent and thorough effort, the Bureau was unable to ascertain the existence of a federally recognized accrediting body for the naturopathic medical profession that was equivalent to the Council on Naturopathic Medical Education. This ensures that applicants for licensure have attended consistent educational programs, which include minimum educational standards.

Article 6. Practice of Naturopathic Medicine

17. Adds Section 4232.

This section specifies the requirements for giving a patient informed consent. This informs a patient that he/she is receiving naturopathic medical services from a certificate holder or student.

18. Adds Section 4234.

This section specifies that scope of the medical services that a licensed naturopathic doctor may provide or perform. This provides licensees with greater clarity about what procedures or services are or are not within the statutory scope of practice.

19. Adds Section 4236.

This section establishes the requirements for a licensed naturopathic doctor to prescribe drugs. This section also specifies the requirements for a drug order issued by a naturopathic doctor. This allows the Bureau to issue a drug furnishing number to those licensees who have meet the required pharmacology training.

Article 7. Fees

20. Adds Section 4240.

This section establishes the fees that are required for applications, initial licensure, renewal of a current or expired license, duplicate licenses and the fee for processing fingerprint cards. This allows the Bureau to collect specific fees from applicants, licensees, and certificate holders in order to fund the administrative and operating functions of the Act.

Article 8. Citations

21. Adds Section 4242.

This section establishes the authority to issue citations and timeframes for purging a citation. Also specifies that citations will be disclosed to the public upon request. This allows the Bureau to enforce the provisions of the Act by issuing citations to licensees who violate any provision of the Act or regulations and to disclose those citations to an inquiring member of the public.

22. Adds Section 4244.

This section specifies the format of a citation and the process for issuing a citation. This ensures consistency in the elements of a citation.

23. Adds Section 4246.

This section establishes minimum and maximum amounts for the administrative fines contained in a citation. This allows the Bureau to collect administrative fines for citations issued to licensees.

24. Adds Section 4248.

This section specifies the factors that the Chief of the Bureau shall consider in assessing the amount of an administrative fine. This allows the Bureau discretion when determining the amount of an administrative fine to a cited licensee.

25. Adds Section 4250.

This section establishes the process for contesting a citation and establishes that a person issued a citation that has had the citation modified in an informal conference cannot request another informal conference to contest the same citation. This allows a licensee who has been cited by the Bureau to challenge the citation.

26. Adds Section 4252.

This section establishes the timeframes for complying with an order of abatement and specifies the consequences of failing to honor those timeframes. This provides notice to licensees regarding requesting extensions of time and a basis for disciplinary action.

27. Adds Section 4254.

This section establishes the authority for the Bureau to issue citations for unlicensed activity and fine amounts of such citations. This allows the Bureau protect the provisions of the Act against unlicensed practice.

Article 9. Enforcement

28. Adds Section 4256.

This section defines the substantial relationship criteria for the Bureau to use when denying, suspending, or revoking a license based upon an act

or crime committed by an applicant or licensee. This allows the Bureau to protect the health, safety and welfare of the public from a licensee or certificate holder who is unfit to practice or has committed a specified criminal act.

29. Adds Section 4258.

This section establishes the criteria that the Bureau must follow when considering the denial of a license or when evaluating the rehabilitation of the applicant. This allows the Bureau to apply consistent standards when considering fitness for licensure.

30. Adds Section 4260.

This section defines unprofessional conduct for which the Bureau may take disciplinary action against a licensee. This provides notice to licensees of the types of unprofessional conduct activities that warrant disciplinary actions against a licensee or certificate holder.

Article 10. Advertising

31. Adds Section 4262.

This section authorizes licensees to advertise naturopathic medical services with the specified restrictions. This protects the public from false or misleading information from a licensee.

Article 11. Naturopathic Corporations

32. Adds Section 4264.

This section establishes that the authority of the laws relating to naturopathic corporations does not alter the responsibilities of a naturopathic doctor to his or her patients. This allows a licensee to be a shareholder, officer, director, or professional employee of a naturopathic corporation without jeopardizing the Bureau's enforcement power pertaining to the standards of professional conduct of its licensee.

33. Adds Section 4266.

This section sets standards for naturopathic corporation insurance policies and establishes the liability of the shareholders of a naturopathic corporation under specified conditions. This requires the naturopathic corporation to provide adequate security by insurance for claims against it by its patients.

35. Adds Section 4268.

This section establishes the requirements of ownership and transfer of ownership of the shares of a naturopathic corporation. This allows the naturopathic corporation to sell shares of a shareholder (licensee) who dies or becomes disqualified.

Updated Information:

The Initial Statement of Reasons is included in the file. A public notice for comments on proposed regulations was sent to all interested parties and posted on the Bureau's website. A public hearing was held on February 23, 2005, where Bureau's staff heard testimony. Minutes of the hearing are included in the file.

Upon further review of the proposed language and based on the oral testimony and written comments received as summarized under *Objections or Recommendations/Responses* of this document, the Bureau elected to make additional changes for clarity purposes to the proposed language for sections 4204, 4206, 4212 (a) (8), 4212 (a) (9), 4220 (a), 4226 (d), 4226 (e), 4228 (b), 4236 (a)-(e), and 4240 (a)-(f) as follows:

Section 4204 was modified to reflect that a licensee or certificate holder shall designate an address of record for public information.

Section 4206 was modified to alphabetize the definitions.

Section 4212 (a) (8) was modified to clarify fingerprinting through Live Scan services or certified fingerprints for out-of-state applicants.

Section 4212 (a) (9) was modified to clarify a photograph of applicant should be passport-size and taken within six months preceding the filing of the application.

Section 4220 (a) was modified to add "*or NABNE deems the form of the examination "era appropriate,"*" to address applicants who took and passed earlier forms of the NPLEX.

Section 4226 (d) was added to limit the renewal of an expired license to within three years after its expiration and require the licensee to pay unpaid renewal fees and late fees as a condition precedent to renewal.

Section 4226 (e) was added to explain the process to apply for licensure if a license is not renewed with three years after its expiration.

Section 4228 (b) was modified to add "*for the renewal period preceding the request to reactive,*" clarifying the continuing education required when reactivating an inactive license.

Section 4236 (a)-(e) was modified to clarify the process of obtaining a furnishing number prior to the furnishing and ordering of drugs, as well as other preconditions.

Section 4240 was modified to reflect the initial licensing fee would be prorated based on the applicant's birth month and month the license is issued. An initial licensing fee schedule was added to depict the prorated amount for each month.

The above-mentioned sections were included in the May 18, 2005 proposed modification notice and text.

Furthermore, written comments from the public were received during the 45-day comment period and are summarized under *Objections or Recommendations/Responses* of this document.

The Bureau issued a 15-day modified text proposal. The modified text was mailed to those individuals who provided public comment during the initial public comment period and posted the notice and modified text on the Bureau's website. During this 15-day public comment period, from May 18, 2005 through June 2, 2005, the Bureau received no further comments.

Local Mandate:

This action does not impose a mandate on local agencies or school districts.

Small Business Impact:

This action will not have a significant adverse economic impact on small businesses.

Consideration of Alternatives:

No reasonable alternative which was considered or that has otherwise been identified and brought to the attention of the Bureau would be either more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed regulations and the modified text.

Objections or Recommendations/Responses:

On February 23, 2005, the Bureau heard testimony from the public. A copy of the hearing minutes is included in the rulemaking file.

A. Summary of Oral Comments:

Oral comments received at the February 23, 2005 public regulatory hearing are summarized as follows:

1. Mr. Jeff Goin, President, The Coalition for Natural Health, spoke to his written comments submitted to the Bureau in regards to Section 4254 Unlicensed Practice. The Bureau's responses are set out below.
2. Ms. Gloria St. John, Executive Director, California Naturopathic Doctors Association, spoke to her written comments submitted to the Bureau in regards to Sections 4206, 4212 (a) (7) and (a) (7)(B), 4222 (d) (2), 4234 (a) (2), 4234 (a) (3), 4237, and 4242 (d). The Bureau's responses are set out below.
3. Ms. Deborah Mattos, Legislative Advocate, Southern California University of Health Sciences in Whittier, spoke only to introduce herself and made no comments specific to the proposed regulations.

B. Summary of Written Comments

The Bureau received written comments from three individuals during the 45-day public comment period. The following is a summary of the written comments received and the Bureau's response to the written comments.

1. Mr. Jeff Goin, President, The Coalition for Natural Health, suggested amending Section 4254 as follows: change the title from "Unlicensed Practice" to *"Unlawful Use of Title"* and replace text in the first sentence that reads "is acting in the capacity of a licensee under the jurisdiction of the Bureau" with *"violates Section 3660 and 3661 of the California Business and Professions Code"*.

The Bureau rejected Mr. Goin's suggestions because the Bureau's authority to cite unlicensed persons is broader than just for the unlawful use of title.

2. Ms. Gloria St. John, Executive Director, California Naturopathic Doctors Association, suggested amending, adding, or deleting sections 4206, 4212 (a) (7) and (a) (7)(B), 4222 (d) (2), 4234 (a) (2), 4234 (a) (3), 4237, and 4242 (d) as follows:
 - a. Amend Section 4206 to add a definition for "drug" by adding subsection *"(j) Drug: Any substance cited pursuant to state section code 4022, 4023, and 4025 if its label is required to bear the statement "Rx only" or similar intended wording."*

The Bureau rejected this suggestion because "drug" is defined in its entirety in Section 4025 of the Business and Professions Code.

- b. Amend Section 4212 (a) (7) to add *"Section 3640.7 of the Code"*.

The Bureau accepted this suggestion, and also added the words “*Section 4236*” for clarity, and included it in the May 18, 2005 proposed modification notice and text.

- c. Amend Section 4212 (a) (7) (B) to add “*pharmacy*”.

The Bureau accepted this suggestion and included it in the May 18, 2005 proposed modification notice and text.

- d. Amend Section 4222 (d) (2) to replace the word “attach” with “*make available to the Bureau upon request.*”

The Bureau rejected this suggestion because Section 3635 (a) of the Business and Professions Code states “...the bureau shall require the satisfactory completion of 60 hours of approved continuing education biennially.” The Bureau feels it is essential for all licensees to provide written evidence that they have completed the required continuing education courses before their licenses are renewed by the Bureau.

- e. Amend Section 4234 (a) (2) to replace “The independent prescription and administration of epinephrine to treat anaphylaxis, as” with “*Those functions.*”

The Bureau rejected this suggestion because it did not bring any more clarity or make specific the intent of the law than that of the proposed regulations.

- f. Delete Section 4234 (a) (3) that reads “*This independent prescription of natural and synthetic hormones, as specified in Section 3640.7 of the Code.*”

The Bureau rejected this suggestion because it did not bring any more clarity or make specific the intent of the law than that of the proposed regulations.

- g. Add Section 4237 to read “*Section 4237. Prescribing Drugs. (a) the prescribing of drugs by licensees, in accordance with Section 3640.7 is conditional on all the following. 1) Registration with the United States Drug Enforcement Agency, when applicable. 2) The issuance of a furnishing number to the licensee by the Bureau.*”

The Bureau accepted this suggestion and placed it in Section 4236 (c) with additional text for clarity and included it in the May 18, 2005 proposed modification notice.

- h. Amend Section 4242 (d) to add “NMD” to list of “reserved” titles. The Bureau rejected this suggestion. “NMD” is an acronym for “naturopathic medical doctor,” the complete title which is apparently permitted for licensees by Section 3660(a) of the Code. The Bureau believes that it can already cite an unlicensed person from using the acronym pursuant to Section 3660(b) of the Code. The acronym, however, is a designation that would tend to indicate the practice of medicine, a practice that is prohibited by Section 3661 of the Code. Accordingly, the Bureau does not wish to indicate that the acronym is “reserved” for licensees, and has the authority to cite a licensed person for its use.
- 3. Ms. Anna Nordin, Naturopathic Doctor in El Paso, Texas, suggested amendments to Senate Bill 907 (Chapter 485, Statute 2003), Bureau forms, and proposed regulations. The Bureau considered only those comments that related to the proposed regulations as follows:
 - a. Amend Section 4220 (c) (2) to add “*an approved Canadian naturopathic medical school prior to 1995*”.

The Bureau rejected this suggestion because Section 3633.1 of the Business and Professions Code clearly states the following:

“The bureau may grant a license to an applicant who meets the requirements of Section 3630, **but who graduated prior to 1986**, pre-NPLEX, and passed a state naturopathic licensing examination. Applications under this section shall be received not later than December 31, 2007.”

To consider Ms. Nordin’s suggestion, the statute would have to be changed.

- b. Amend Section 4220 (c) (3) to add “*a Canadian provincial naturopathic board examination*” within the first sentence and add “*Canadian provincial board exam*” within the second sentence.

The Bureau rejected this suggestion because Section 3633.1 of the Business and Professions Code clearly states the following:

“The bureau may grant a license to an applicant who meets the requirements of Section 3630, **but who graduated prior to 1986**, pre-NPLEX, **and passed a state naturopathic licensing examination**. Applications under this section shall be received not later than December 31, 2007. “

“State” as defined by §21 of the Code includes only the states of the United States, the District of Columbia, and the territories.

To consider Ms. Nordin’s suggestion, the statute would have to be changed.

There were no other individuals who submitted written comments. Furthermore, there were no other written comments received during the 15-day proposed modification period that began on May 18, 2005 and ended on June 2, 2005.